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WITNESS my hand this Seventh day of December 2004

LEANNE MYNOTT

MANAGER EXAMINATION SUPPORT

AND SALES

AUSTRALIA PATENTS ACT 1990

Provisional Specification

Invention Title:

THE MONITORING OF VITAL SIGNS

The Invention is described in the following statement:

TITLE OF THE INVENTION

The Monitoring of Vital Signs

FIELD OF THE INVENTION

This invention relates to the monitoring of vital signs. More particularly, this invention relates to a device for monitoring vital signs and to a system for monitoring vital signs.

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BACKGROUND OF THE INVENTION

Monitoring a subject's vital signs is an important aspect of disease control and sports training.

With disease control this is presently generally carried out at a monitoring centre, where a subject can be connected to equipment such as a 12-lead electro-cardiogram (ECG), which is commonly used. For home monitoring, a holter monitor is used over longer periods such as 24 hours to determine if a cardiac event occurs during that time. Other equipment such as oximeters can also be used to monitor blood oxygen level. Pulse oximeters can be used to monitor both pulse rate and blood oxygen level. It will be appreciated that there are many other forms of equipment that can be used to monitor a subject's health. Some further examples are blood pressure monitors and blood-glucose monitors.

It has now become possible for subjects to monitor various aspects of their health from home. This is achieved by providing the subject with monitoring devices that are relatively easy to fit and to use. Examples of such devices are ECG monitors and blood pressure monitors.

In spite of the fact that there now exists a proliferation of self-monitoring devices, it often remains difficult for a subject to make a decision regarding the result of such self-monitoring. Furthermore, it is difficult for a subject continuously to monitor various characteristics to obtain a pattern that may be important, without being substantially inconvenienced.

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Applicant therefore believes that it is desirable that a means be provided whereby a healthcare professional can monitor such characteristics without causing excessive inconvenience to a subject. Still further, Applicant believes that it is desirable that a means be provided whereby a historical record of such characteristics can be collated for analysis at a later date.

As far as physical training is concerned, monitoring of such vital signs as heart rate has long been a standard tool used by coaches to determine the performance and physical capacity of sportsmen and women. In the case of monitoring heart rate, the subject wears a heart rate monitor that can be strapped to the chest. Such monitors are capable of transmitting a signal a metre or two, the signal carrying data representing a heart rate of the subject. It follows that, in order for the coach to be informed of the heart rate, it is necessary for the subject verbally to advise the coach of the heart rate. It will be appreciated that this is not always desirable, particularly in competitive situations, where the subject may not be able to advise the coach of his or her heart rate.

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Each subject has a different aerobic threshold. Whether or not a subject has reached his or her threshold can be determined by having knowledge of the subject's optimal heart rate and maximum heart rate. Applicant believes that it would be desirable for a means to be provided whereby a coach could determine the heart rate of a subject without having to communicate directly with the subject. Applicant believes further that it would be desirable for a means to be provided whereby a historical record of a subject's heart rate could be collated for analysis. This applies to other vital signs in addition to heart rate, such as blood-oxygen level; temperature, respiration rate and cardiac output.

Applicant believes that the ability wirelessly to monitor a person's vital signs is highly desirable. There are many reasons for this. For example, wireless monitoring could be used to manage chronic disease to ensure that a chronic condition does not become acute. In this case, wireless monitoring could be used to generate a history relating to one or more vital signs such as heart activity and blood-oxygen level. A medical practitioner could study this history so that a decision can be made as to whether intervention or change of therapy is required.

DEFINITIONS

In this specification, unless otherwise specified, the following words and their derivations will have the associated meanings:

- (a) "Subject" A person whose vital signs are monitored in accordance with this invention.
- (b) "Vital sign" A characteristic relating to the physiology of a subject, such as heart rate, blood-oxygen level and blood sugar level.
- (c) "Wireless communication" Any communication using a protocol suitable for carrying digital data, such as that known as Bluetooth (trade mark), 802.11a, 802.11b and the more recent "Ultra Wide Band" or UWB, but is not limited to these formats or interfaces.
- (d) "Monitoring Centre" Any location where health monitoring can take place, including not only hospitals, clinics and the like, but also locations where operators receive data relating to vital signs of subjects, depending on the application of the invention.
- (e) "Operator" Any person who monitors health characteristics of the subject. Such a person could be some form of medical practitioner, a sports coach or a fitness instructor or trainer.

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SUMMARY OF THE INVENTION

According to a first aspect of the invention, there is provided a monitoring device that includes

a housing;

an input means that is positioned on the housing to receive an electrical signal carrying data representing at least one vital sign of a subject; and

wireless communication circuitry that is positioned in the housing and is connected to the input means for transmitting and receiving wireless signals.

An antenna may be connected to the wireless communication circuitry.

The device may include processing circuitry that is positioned in the housing and connected between the input means and the communication circuitry to receive

the electrical signal and to control operation of the device. The processing circuitry may be configured to carry out algorithmic processes on the signal for analysis. Thus, the processing circuitry may be configured to generate a suitable signal upon the detection of some feature of the signal.

The input means may be a pair of plug sockets mounted on the housing to permit a pair of plugs on electrode leads to be plugged into respective sockets. In particular, the electrode leads may be of the types that are connected to ECG electrodes so that an ECG signal is provided to the processing circuitry.

Instead, or in addition, the input means may include a pair of snap fasteners that are mounted on the housing and are connected to the signal receiving circuitry.

The snap fasteners may be configured to permit a pair of stude of electrocardiographic (ECG) electrodes to be fastened to the housing so that signals detected by the electrodes can be conveyed to the processing circuitry. The snap fasteners may also be configured to permit a chest strap or electrodes of customized clothing to be fastened to the housing. Still further, the snap fasteners may be configured to permit a pair of metal contact electrodes to be fastened to the housing. In this configuration, the monitoring device is simply pressed against the subject so that the metal contact electrodes bear against the subject's body in a suitable location.

It follows that the snap fasteners may be suitably spaced to permit ECG signals to be received from directly connected, disposable electrodes. The housing may be selected to have a minimum weight to permit the housing to be positioned on the subject without any further support.

The housing may be a pair of cover members that clip together to enclose the components. Where the input means is the two plug sockets, the cover members may be shaped to accommodate the plug sockets. Where the input means is the two snap fasteners, the two snap fasteners may be mounted in one of the cover members to be accessible from an internal side of said one of the cover members.

In one embodiment, the input means includes both the plug sockets and the snap fasteners. In this case, said one of the cover members may be provided in two forms. In a first form, said one of the cover members may have a closed face and

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may be shaped to accommodate the plug sockets. In a second form, said one of the cover members may be shaped to cover the plug sockets and may have the snap fasteners mounted in the cover member.

In a further embodiment, the input means includes the plug sockets and metal contact electrodes mounted in the housing to project from the housing. The metal contact electrodes may be suitably spaced so that the device can be placed against the subject's body such that the contact electrodes are able to detect a vital sign of the subject.

The processor circuitry may be configured to carry out an analysis on the ECG signal to detect anomalies, such as atrial fibrillation. The processor circuitry may be configured to generate a signal for transmission by the communication circuitry on detection of said anomalies.

The device may include a memory device that is connected to the processor circuitry to permit data representing the ECG signal over a period of time to be stored. The data may be stored in a manner which would permit downloading of the data to a suitable device that communicates with the processing circuitry via the communication circuitry.

The processor circuitry and the transmission circuitry may be mounted on a printed circuit board (PCB) that is positioned in the housing.

The device may include a power supply in the form of a rechargeable battery.

Various indicators may be mounted on the PCB to be connected to the processing circuitry to indicate a status of the device.

The device may include an event switch that is mounted on the PCB to extend through the housing. The event switch may be connected to the processor circuitry and may be operated by the subject to generate a signal that is transmitted by the communication circuitry.

The device may also incorporate conventional heart rate detection and radio transmitting circuitry to transmit a radio signal carrying heart rate data to a conventional display device, such as that worn on a subject's wrist.

According to a second aspect of the invention, there is provided an accessory for use with the monitoring device described above, the accessory including

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a support member;

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a pair of spaced contact pads positioned on the support member, each contact pad being of a conductive fabric; and

a connection means that is electrically connected to respective contact pads, the connection means being configured so that the input means of the monitoring device can be connected to the contact pads via the connection means.

The connection means may be in the form of a pair of spaced studs so that when the monitoring device includes the snap fasteners, the device can simply be clipped to the support member.

According to a third aspect of the Invention, there is provided a system for monitoring vital signs of a subject, the system including

a monitoring device as described above; and

a receiver for receiving a signal transmitted by the communication circuitry of the monitoring device.

The receiver may be configured to communicate with a monitoring centre to permit monitoring of the wireless signal generated by the communication circuitry.

This can be achieved in a number of different ways. For example, the receiver may be connected directly to the monitoring centre. Instead, the receiver may be internet-enabled to communicate with the monitoring centre via the internet. In another example, the receiver may be capable of communicating wirelessly with the monitoring centre.

The receiver may be provided in a number of different forms. In one form, the receiver may be a personal computer having a wireless input to receive the signal from the monitoring device. It will be appreciated that the personal computer can be programmed in a number of different ways. For example, the personal computer can be programmed to carry out algorithmic processes on the data. The personal computer can be directly wired to the monitoring centre or can be connected to the monitoring centre via the Internet.

Instead of being a personal computer, the receiver may be an applicationspecific device that is configured to receive the signal from the monitoring device. The receiver may be wirelessly connected to the monitoring station, or may be hard-wired to the monitoring station. Still further, the receiver may be connected to the monitoring station via the Internet.

In both cases, the receiver may be configured to process the signal received from the monitoring device and to display data representing that signal in a form that is suitable for reading by an operator. The receiver may further be configured to display the data in a form that is suitable for reading by the subject. It will be appreciated that this will permit the subject to carry out some level of self-monitoring.

In another embodiment, the receiver is in the form of a handheld device. The handheld device may be conventional, such as a PDA, mobile phone or similar device. Instead, the device may be application-specific. In both cases, the handheld device may incorporate a display for displaying the data transmitted by the monitoring device in a form suitable for reading by a subject.

Optionally, the handheld device may be Internet-enabled so that the data can be communicated to the monitoring centre.

In a simple form, the receiver could be an application-specific handheld device that can be used by an operator for downloading data carried by the monitoring device, via a suitable wireless communication protocol.

It will be appreciated that the system would be suitable for two-way communication between the subject and the operator.

According to a fourth aspect of the invention, there is provided a method of monitoring vital signs, the method including the steps of:

receiving an electrical signal representing at least one vital sign from a subject; and

wirelessly communicating a signal carrying data representing at least a feature of the, or each, vital sign to a receiver that is remote from the subject.

The invention is now described, by way of examples, with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

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Figure 1 is an exploded top perspective view of a monitoring device in accordance with the invention.

Figure 2 is an exploded bottom perspective view of the monitoring device.

Figure 3 is a top plan view of a circuit board of the monitoring device.

Figure 4 is an end view of the circuit board.

Figure 5 is a side view of the circuit board.

Figure 6 is a bottom plan view of the circuit board.

Figure 7 is a block diagram of the monitoring device.

Figure 8 is a schematic diagram of a first embodiment of a health monitoring system, in accordance with the invention.

Figure 9 is a schematic diagram of a second embodiment of a health monitoring system, in accordance with the invention.

Figure 10 is a perspective view of a first embodiment of an accessory, in accordance with the invention, for use with the monitoring device of figure 1.

Figure 11 is a perspective outer view of a second embodiment of an accessory, in accordance with the invention, for use with the monitoring device of figure 1.

Figure 12 is a perspective inner view of part of the accessory of figure 11.

20 DETAILED DESCRIPTION OF THE INVENTION

In figures 1 and 2 reference numeral 10 generally indicates a monitoring device or monitor, in accordance with the invention.

The monitor 10 includes a housing 12. The housing 12 includes a top cover 14 and bottom cover 16. A circuit board 18 is interposed between the covers 14, 16 which are fastened to the circuit board 18 with suitable fastening formations 20.

The monitor 10 includes an input means 21 (figure 7) in the form of a pair of plug sockets 22 that are mounted on the circuit board 18. The plug sockets 22 are configured to engage plugs (not shown) of leads that are connected to ECG electrodes. The plug sockets 22 are positioned at an end of the circuit board 18.

The input means 21 also includes a pair of spaced, spring-loaded pins 24 that are mounted on the circuit board 18. It follows that the monitor 10 can either receive an ECG signal from the plug sockets 22 or the spring-loaded pins 24.

The monitor 10 is provided with three different forms of bottom cover 16. In a first form, the bottom cover 16.1 has a pair of recesses 26. The recesses 26 correspond with a pair of recesses 28 in the top cover 14 to define a pair of openings for the plug sockets 22. Furthermore, a panel 30 of the bottom cover 16.1 serves to prevent access to the pins 24.

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In a second form, the cover 16.2 has a pair of spaced snap fasteners 32 mounted in a panel 34 of the cover 16.2. The snap fasteners 32 are positioned sufficiently far apart to be snap-fastened to respective studs (not shown) of disposable ECG electrodes. The pins 24 are aligned with the snap fasteners 32 and positioned such that, when the covers 14 and 16.2 are connected together, the pins 24 bear against respective snap fasteners 32. The monitor 10 is configured to be sufficiently light so that when the snap fasteners 32 are connected to the ECG electrodes, the electrodes serve to support the monitor 10 in position without the need for further support.

The cover 16.2 has a pair of tongues 36 that are configured to be received in respective recesses 28 when the housing 12 is assembled. Thus, when the snap fasteners 32 are to be used to receive the ECG signal, the plug sockets 22 are covered. In the alternative configuration, the cover 16.1 serves to protect a wearer against possible electrical shock from exposure to the pins 24.

The device 10 can be supplied with a pair of metal contact electrodes 136. Each contact electrode 136 has a stud 138 that is shaped to clip into one respective snap fastener 32. Thus, it will be appreciated that the device 10 can be used by simply positioning the device 10 against the subject with the electrodes 136 bearing against the subject in a sultable position.

In a third form, the bottom cover 16.3 has metal contact electrodes 140 mounted in a panel 142 of the cover 16.3 to extend outwardly from the panel 142 and also to make contact with the pins 24 when the cover 16.3 is clipped to the top cover

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14. In this form, the device 10 can also be positioned against the subject with the electrodes 140 bearing against the subject in a suitable position.

The cover 16.3 also has tongues 144 that serve the same purpose as the tongues 36 of the cover 16.2.

The monitor 10 includes processing circuitry in the form of a microprocessor 38 that is mounted on the circuit board 18. The microprocessor 38 is connected to the input means 21 via an ECG signal amplifier 40 (figure 7) to receive an amplified ECG signal from the input means 21.

The monitor 10 includes wireless communication circuitry in the form of a Bluetooth (trade mark) module 42. The Bluetooth module 42 is connected to the microprocessor 38 to receive data for transmission from the microprocessor 38 and also to receive signals transmitted to the monitor 10.

The monitor 10 further includes a low-frequency antenna 44 to receive and to transmit signals.

The monitor 10 includes a power supply 46 to power operation of the monitor 10. The power supply 46 includes a rechargeable battery 48 that is connected to the microprocessor 38 and a battery charger 50 that is connected to the battery 48 and to the microprocessor 38 for control of a recharging process.

As can be seen in figures 1 and 2, the battery 48 is engageable with the circuit board 18, via a battery mount 52.

A power switch 54 is mounted on the circuit board 18 and is connected to the microprocessor 38 to permit the monitor 10 to be turned on or off. The power switch 54 is in the form of a push switch that extends through an opening 56 in the top cover 14.

An event switch 58 is also mounted on the circuit board 18 and is connected to the microprocessor 38. The event switch 58 is in the form of a push switch that extends through an opening 60 in the top cover 14. The microprocessor 38 is configured to generate a predetermined signal for transmission by the module 42 when the switch 58 is depressed.

The monitor 10 includes a power status LED 62, a heart status LED 63 and a communication status LED 66 all connected to the microprocessor 38.

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In use, the monitor 10 is either fastened to a subject by clipping onto a pair of disposable electrodes that are fastened at a suitable location to the subject or by having electrode plugs received in the plug sockets 22. It will readily be appreciated that the monitor 10 can be fastened to the subject in a number of other conventional ways, if necessary. For example, the monitor could be connected to a strap, as is conventionally used in sport and fitness training. Instead, the monitor 10 could be connected to recently developed "electrode fabric" worn by the subject.

In a medical embodiment, the microprocessor 38 is configured to analyse the ECG signal to detect anomalies, such as atrial fibrillation. Upon the detection of such an anomaly, the microprocessor 38 is configured to generate a signal that is transmitted by the module 42 to a receiver.

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In a coaching/training embodiment, the microprocessor 38 is configured simply to transmit the ECG signal to a receiver via the module 42.

Optionally, the monitor 10 can include a memory module, shown in dotted lines 64 in figure 7 that is connected to the microprocessor 38. The microprocessor 38 can be configured to store a record of the ECG signal, or characteristics thereof, in the memory module 64. The microprocessor 38 can be configured so that, upon receipt of a suitable signal via the module 42, the microprocessor 38 downloads the contents of the memory to a receiver, via the module 42.

It will be appreciated that in a simple form, an operator can communicate directly with the monitor 10 to download data from the memory module 64.

It will be appreciated that the Bluetooth module 42 readily permits communication with the subject. This can be simple communication such as the generation of a sound, via conventional hardware, when the subject is required to take some form of action such as taking a dosage (medical) or slowing down (coaching/training). Instead, the communication can also be vocal, by connecting suitable conventional telephonic hardware to the Bluetooth module 42. This would permit the monitor 10 to be used either for monitoring the ECG signal or for permitting the operator to communicate telephonically with the subject or for both monitoring and communicating.

The monitor 10 can be used as a conventional heart rate monitor. Thus, the microprocessor 38 is configured to receive a signal representing the heart rate from the ECG amplifier 40 via the input means 21 and to generate a signal that carries data representing the heart rate. The monitor includes a conventional short-range radio transmitter 132 that is connected to the microprocessor 38 to transmit the signal to a display 134. The display 134 can, conventionally, be in the form of a wrist display.

In figure 8, reference numeral 70 generally indicates a first embodiment of a system, in accordance with the invention, for monitoring vital signs. With reference to figures 1 to 7, like reference numerals refer to like parts, unless otherwise specified.

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In the system 70, the monitor 10 is connected to a subject 72 in any suitable manner, as described above. The system 70 includes a receiver 74 that is configured to receive and transmit signals to the monitor 10, via the Bluetooth module 42 and a suitable antenna 76. The receiver 74 can be in a number of different forms.

In one embodiment, the receiver 74 is a personal computer (PC). In this case, the PC includes a suitable modern that is connected to the antenna 76 to communicate with the monitor 10. The PC can be programmed to display a visual signal representing the ECG signal. Such a signal is usually only capable of being read by professional operators. Accordingly, the PC can be programmed so that the visual signal is capable of being interpreted by the subject 72. This allows some level of self-monitoring. In certain cases, the PC can be programmed to analyse the signal and to detect anomalies, such as atrial fibrillation, and to display the presence of such anomalies, also in a form that can be interpreted by the subject 72.

It will be appreciated that the receiver 74 can be provided in a number of different forms depending on the application of the invention. For example, the PC can be portable where necessary, to be used by the operator "in the field" such as when the operator makes house calls on chronically ill subjects or where the operator is a coach or trainer that is monitoring the subject as they train or compete.

In this example, the receiver 74 is connected to a monitoring centre indicated at 78 to communicate with the monitoring centre 78. The manner in which the receiver 74 can be connected to the centre 78 is highly variable. For example, the

receiver 74 can be configured to be connected to the centre 78 via the Internet. In another example, the receiver 74 can be wired directly to the centre 78. In yet another example, the receiver 74 can communicate wirelessly with the monitoring centre 78.

In figure 9, reference numeral 90 generally indicates a second embodiment of a system for monitoring vital signs. With reference to figures 1 to 8, like reference numerals refer to like parts, unless otherwise specified.

The system 90 is particularly suitable for mobile monitoring of vital signs. In this case, the receiver is in the form of a handheld wireless communications device 92. The device 92 can be provided in a number of different forms. For example, in one form, the device 92 can be an application-specific device that is used by an operator for downloading data from the memory module 64 or simply for recording the signal transmitted by the Bluetooth module 42. In another example, the device 92 is a mobile telecommunications device such as a mobile phone or PDA. The device 92 is configured to receive a signal from the Bluetooth module 42 and to transmit a signal to the module 42.

In the example shown, the device 92 communicates with the monitoring centre 78 via a mobile relay station network, indicated at 94.

It will readily be appreciated that the systems 70, 90 cover a wide variety of different embodiments that can be used depending on the required application.

For example, the system 70 can be used by an operator at the monitoring centre 78 to communicate with a chronically ill subject to ensure that the subject takes medication on time. The operator can also monitor the subject's vital signs to ensure that the subject can be treated preventatively if necessary.

The system 90 is particularly useful if used in coaching or training. In such an application, the subject 72 could wear the device 92, together with the monitor 10. It follows that the monitoring centre 78 could be a location for the operator in the form of a coach or trainer, who could monitor the vital signs of the subjects and also, as described above, communicate verbally with the subjects.

Applicant submits that the monitor 10 could be configured to monitor other vital signs, such as blood-oxygen levels. Furthermore, the monitor 10 could be configured to monitor vital signs such as heart rate and blood-oxygen at the same time.

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In figure 10, reference numeral 100 generally indicates a first embodiment of an accessory, in accordance with the invention, for use with the monitor 10.

The accessory 100 includes a support member in the form of a sheet 102 of a flexible material. The material may be leather, vinyl or the like and is configured to have an aesthetically pleasing appearance.

The sheet 102 is foldable about a fold line 104 that divides the sheet 102 into a first portion 106 and a second portion 108. The accessory includes a pair of contact pads 110 of a conductive fabric. One of contact pads 110.1 is positioned on the first portion 106, while the other contact pad 110.2 is positioned on the second portion 108.

A connecting means in the form of a pair of spaced studs 112 are mounted on the first portion 106. Each stud 112 is electrically connected to a respective contact pad 110. The studs 112 are positioned and configured so that the bottom cover 16.2 can be clipped onto the studs 112, via the snap fasteners 32.

The contact pads 110 each have elongate tails that extend within the sheet 102 to be crimped to the studs 112. In particular, the contact pad 110.1 is crimped to a left-hand stud 112.2 while the contact pad 110.2 is crimped to a right-hand stud 112.1.

The conductive fabric of the contact pads 110 is a stretch conductive fabric. In particular, the conductive fabric is a medical grade, silver plated fabric. The fabric itself is a combination of Nylon and the fabric known as Dorlastan.

In use, the subject places each hand on a respective contact pad 110. The monitor 10 is thus able to detect the relevant vital signs of the subject via the contact pads 110 and the studs 112.

It will be appreciated that the accessory 100 obviates the need for a subject to wear the device 10. In some circumstances, it may not be necessary for the subject to be monitored on a continuous basis. The accessory 100 allows the subject to carry out self-monitoring. Alternatively, an operator can use the accessory 100, where necessary, to obtain data relating to the subject's vital signs.

In figures 11 and 12, reference numeral 120 generally indicates a second embodiment of an accessory, in accordance with the invention, for the device 10.

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With reference to figure 10, like reference numerals refer to like parts, unless otherwise specified.

The accessory 120 includes a support member in the form of a chest strap 122.

A connecting means in the form of a pair of spaced studs 124 are mounted on the strap 122 to extend from an outer surface 126 of the strap 122. The studs 124 are shaped and positioned so that the bottom cover 16.2 can be clipped to the strap 122, via the fasteners 32.

A pair of contact pads 128 is positioned on an inner surface 130 of the strap 122. The contact pads 128 are of the same material as the contact pads 110 and are connected to the studs 124 in a similar manner.

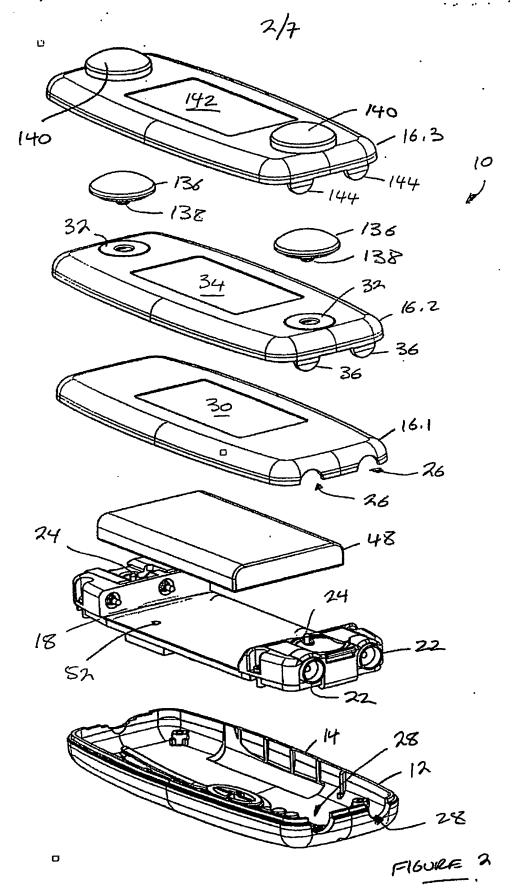
Applicant believes that the invention provides a number of significant advantages over presently available equipment. These are based on the fact that the invention provides a means whereby vital signs or data relating to vital signs can be transmitted to a receiver in a form suitable for further transmission or analysis.

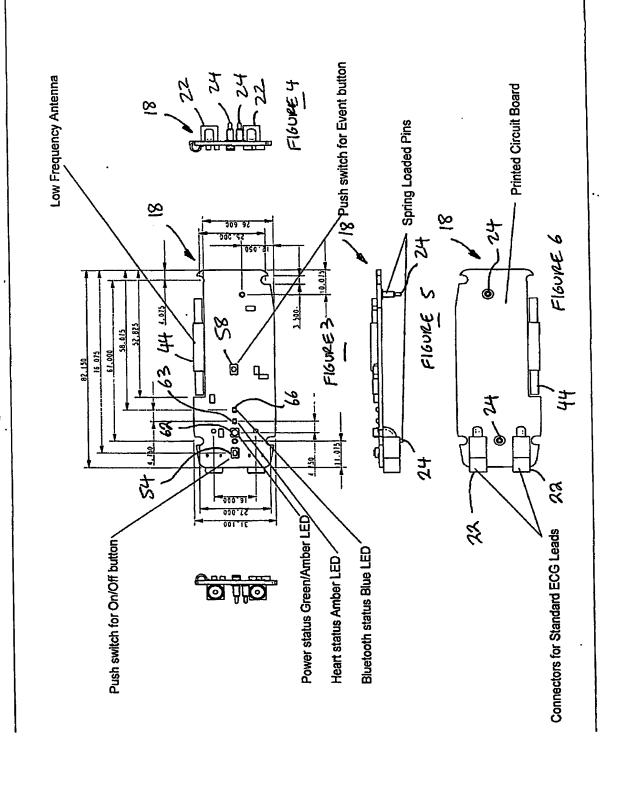
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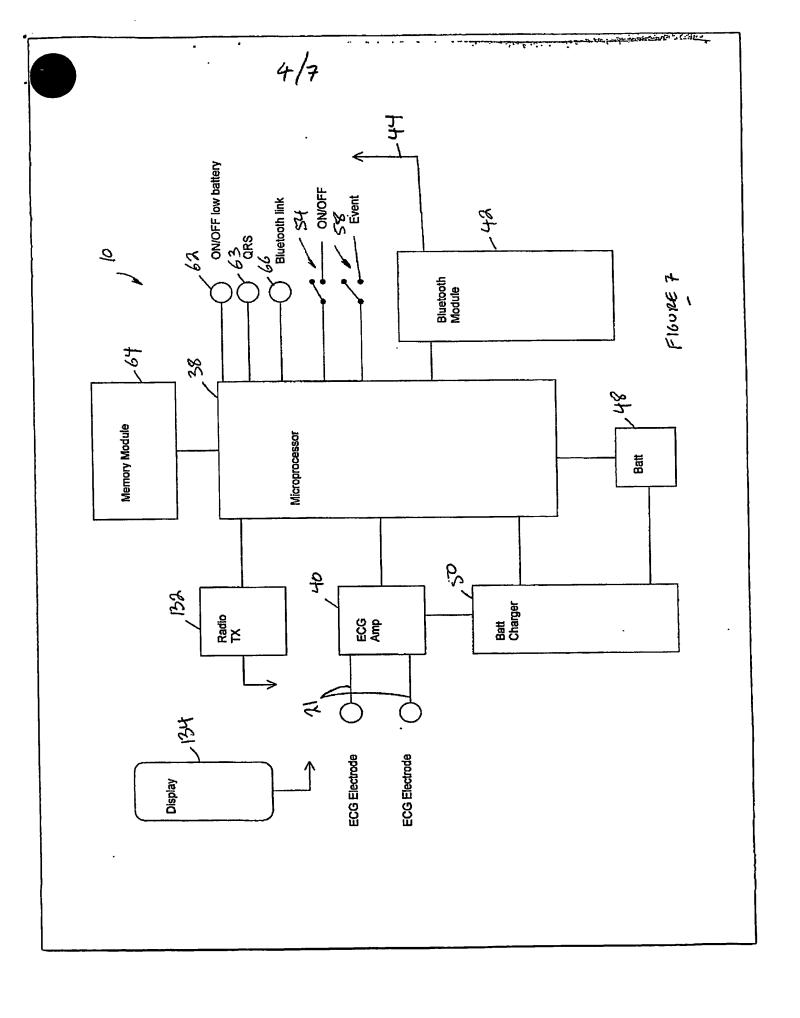
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FIGURE 1

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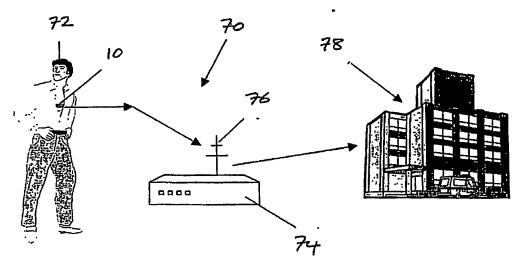


FIGURE 8

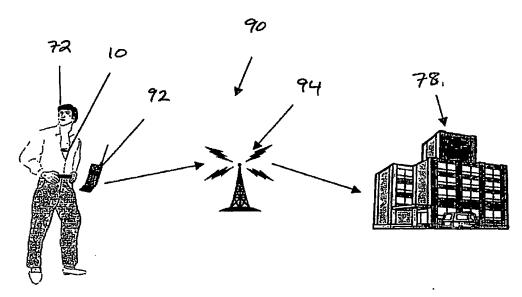


FIGURE 9

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/AU04/001620

International filing date: 18 November 2004 (18.11.2004)

Document type: Certified copy of priority document

Document details: Country/Office: AU

Number: 2003906345

Filing date: 18 November 2003 (18.11.2003)

Date of receipt at the International Bureau: 22 December 2004 (22.12.2004)

Remark: Priority document submitted or transmitted to the International Bureau in

compliance with Rule 17.1(a) or (b)



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